NOV 1 9 2001

K012873

Section 15

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CRF 807.92.

1. **Submitter's name, address, telephone number, contact person, and date summary prepared**

   a. Bausch & Lomb, Inc.
   9342 Jeronimo Rd.
   Irvine, CA 92618

   b. Contact Person: Penni L. Pannell
   Manager, Regulatory Affairs

   Penni L Pannell

   c. Date Summary Prepared: August 24, 2001

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: Documenting Laser Slit Lamp
   b. Classification Name: Ophthalmic Slit Lamp

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company:	Talia Technology, LTD.
Device:	Talia Laser Slit Lamp
510(k)	K930518
Date Cleared:	January 25, 1994

Company:	Nidek Incorporated
Device:	Anterior Eye-Segment Analysis System
510(k)	K991284
Date Cleared:	August 6, 1999

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant**

physical and performance characteristics (design, material, physical properties):

The Documenting Laser Slit Lamp is a non-invasive, hand held diagnostic instrument designed to take photographs of the anterior eye segment using an AC- powered slit lamp biomicroscope. The system contains an illumination device, image-capturing device used for slit image photography. The image is captured on the computer, viewed as still photographs or in a series of images in a video format. The patient data and images are displayed, stored and retrievable.

5. Statement of intended use:

The Documenting Laser Slit Lamp is a diagnostic instrument using an AC-powered slit lamp biomicroscope designed to examine the eye through a control diaphragm a thin, intense beam of light.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The intended use for all three devices is to examine and take photographs of the eye. All devices utilize the same or similar operating principles, in that they contain an optical system, a source of illumination for observation, source of illumination for photography and photographic mediums.

7. Brief summary of nonclinical tests and results:

The Documenting Laser Slit Lamp has been tested to and meets the EN/IEC 601 safety and electromagnetic compatibility standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Penni L. Pannell
Manager, Regulatory Affairs
Bausch & Lomb
9342 Jeronimo Road
Irvine, CA 92618

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Re: K012873
Trade/Device Name: Documenting Laser Slit Lamp, DP 2010
Regulation Number: 21 CFR 886.1850
Regulation Name: Slit Lamp
Regulatory Class: I I
Product Code: HJO
Dated: August 24, 2001
Received: August 27, 2001

Dear Ms. Pannell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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510(k) Number (if known):

Device Name: Documenting Laser Slit Lamp

Indications for Use:

The Documenting Laser Slit Lamp is a diagnostic instrument using an AC-powered slit lamp biomicroscope designed to examine the eye through a control diaphragm a thin, intense beam of light.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl Kaufman

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012873